DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2015

Osteonic Co., Ltd
C/O Ms. Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
2651 E. Chapman Ave., Ste. 110
Fullerton, CA 92831

Re: K140037
Trade/Device Name: Optimus CMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code**:** JEY, DZL
Dated: December 9, 2014
Received: December 12, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k140037

Device Name
OPTIMUS CMF SYSTEM

Indications for Use *(Describe)*

Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including:
1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: Jan 15, 2015

1. Applicant / Submitter:

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2. Submission Correspondent

Priscilla Chung
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3. Device:

- Proprietary Name – OPTIMUS CMF SYSTEM
- Common Name – Dental Bone Plate & Screw System
- Classification Name – Dental Bone Plate
  Screw, fixation, intraosseous

4. Predicate Device:

- LeForte System Bone Plate & Screw by Jeil Medical Corporation (K112457)
- Synthes Matrix Mandibule Plate and Screw System by Synthes Inc. (K113567)
- Biomet Microfixation Facial Plating System by Biomet Microfixation (K121589)
- Synthes (USA) Midfacial System by Synthes (USA) (K953806)
- Synthes 1.3mm Self-Drilling Screw by Synthes (USA) (K983485)
- Leibinger IMF Screw by Howmedical Leibinger, Inc. (K963030)
- Synthes (USA) Craniofacial Plates by Synthes (USA) (K040272)
- Leforte System Bone Plate by Jeil Medical Coporation (K091679)

5. Product Code & Regulation Number:

- JEY (21CFR872.4760)
- DZL (21CFR872.4880)

6. Description:

The OPTIMUS CMF SYSTEM comprises plates and screws. The plate thickness sizes range from 0.4 to 2.6mm. They are made of unalloyed Titanium (ASTM F67) and anodized in

four colors (silver, blue, green, and gold). The diameters of the screws range from 1.3 to 2.7mm, while lengths range from 3.0 to 20.0mm. They are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and anodized in six colors (light blue, silver, purple, blue, gold and green).
The plates and screws are single use only, non-sterile products. They must be sterilized before use.

7. Indication for use:

Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed.

8. Non-Clinical Testing:

The following tests were performed to validate the performance and the safety of the subject device and the test results supported substantial equivalence to the predicate devices.

- 4-Point Bending test in accordance with ASTM F382-99(2008)e1
- Torsion and Axial Pullout Strength Test in accordance with ASTM F543-13e1
- Cytotoxicity test in accordance with ISO 10993-5
- Sensitization test in accordance with ISO 10993-10
- Genotoxicity test in accordance with ISO 10993-3
- Implantation test in accordance with ISO 10993-6
- Sterilization validation test in accordance with ANSI/AAMI ST79, ISO 17665-1, ISO 11737-1, and USP 30-NF25 <61> Microbial Limited Test.

9. Substantial Equivalence:

The subject and predicate device(s) share the same intended use, primary design and equivalent material of manufacture. Any minor differences do not impact device performance as compared to the predicate devices and demonstrate that the Optimus CMF System is substantially equivalent to the predicate devices. The performance test results support that the subject device performs as well as the predicate devices.

	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Predicate Device 5	Predicate Device 6	Predicate Device 7	Predicate Device 8
Company	OSTEONIC Co., Ltd.	Jeil Medical corporation	Synthes	Biomet Microfixation	Synthes	Synthes	Howmedica Leibinger Inc.	Synthes	Jeil Medical Coporation
Device Name	OPTIMUS CMF SYSTEM	LeForte System Bone Plate & Screw	MatrixMANDIBULE Plate and Screw System	Biomet Microfixation Facial Plating System	SYNTHES (USA) MIDFACIAL SYSTEM	Synthes 1.3mm Self-Drilling Screw	Leibinger IMF Sscerw	SYNTHES (USA) CRANIOFACIAL PLATES	LEFORTE SYSTEM BONE PLATE
510(K) #	N/A	K112457	K113567	K121589	K953806	K983485	K963030	K040272	K091679
Class	2	2	2	2	2	2	2	2	2
Product Code	JEY, DZL	JEY, DZL	JEY	JEY	JEY	DZL	DZE	JEY	JEY
Intended Use	Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed.	This device is intended for use in selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin	The SynthesMatrix MANDIBULE Plate and Screw System is intended for oral, maxillofacial surgery: • Trauma • Reconstructi-ve surgery • Orthognatic surgery (surgical correction of deformities)	These devices are implantable bone plates and bone screws for facial procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed	Intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures and selective orthognathic surgery of the maxilla and chin.	Synthes 1.3mm Self-Drilling Screws are intended for selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	Intended for use in temporary maxillomandibular fixation to provide indirect stabilization of the maxilla, mandible or both.	Intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures and selective orthognathic surgery of the maxilla and chin.	This device is intended for use in selective trauma of the mid-face and craniofacial skeleton craniofacial surgery reconstruction procedures and selective orthognathic surgery of the maxilla and chin
Material	Plate – Unalloyed Titanium Screw- Titanium Alloy	Plate –Unalloyed Titanium Screw- Titanium Alloy	Unalloyed Titanium	Plate – Unalloyed Titanium Screw- Titanium Alloy	Unalloyed Titanium	Titanium Alloy	Titanium Alloy	Unalloyed Titanium	Unalloyed Titanium
Surface	Anodizing	Plate: Anodizing Screw: N/A	Anodizing	Plate: N/A Screw: Anodizing	Anodizing	Anodizing	–	Anodizing	Plate: Anodizing
Anodizing color	Light blue, silver, purple,	Silver, blue, green and gold	Silver, blue, green and gold	Silver, magenta, blue, green and	Silver, blue, green and gold	Silver, blue, green and	–	Silver, blue, green and gold	Silver, blue, green and gold

	blue, gold and green			gold		gold			
Single Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sterile	Non sterile	Non sterile	Sterile or non-sterile	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile
Shape and Dimension of plate	Plate has various shapes, length and thickness. Straight, Y, D-Y, X, L, Z, Square, Matrix, Orbital, Chin and Reconstruction types with various lengths. The range of plate's profile is from 0.4 to 2.6mm thickness and 4 colors (silver, blue, green and gold).	Length 5.2~223.5mm Thickness 0.2~2.5mm	The system consists of a variety of plates offered in multiple shape and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient.	The plates that are the subject of this 510(k) submission include variations of straight, angle, curved, L-shape, T-shape, double T-shape, Z-shape, X-shape, Y-shape, double Y-shape, H-shape, triangle, square, rectangle, matrix, mesh, orbital floor, LeFort, and chin options with various lengths and thickness. Plates are offered flat or pre-bent.	The plate size is available in a variety of configurations to accommodate various fracture sites.	–	–	The synthes double adaption plate can be cut or trimmed to the desired length to accommodate various fractures and meet the anatomical need of the patient. The plate has a low profile head, uses 2.0mm self-tapping or self-drilling bone screw and 2.4mm emergency screw.	The system consists of a variety of plates offered in multiple shape and sizes.
Screw Sizes	The diameter of screw is from 1.3 to 2.7mm in lengths of 3.0 to 20.0mm and 6 colors (light blue, silver, purple, blue, gold and green).	Outer(head) diameter 1.2~2.65mm Inner diameter 0.7~1.6mm Length 4.0~18.0mm		Screw range in diameters of 1.0mm to 2.3mm and lengths from 2.0mm to 29.0mm	Screw size is 1.3 or 1.5mm.	Available in lengths ranging from 4~6mm	2.0mm in diameter and ranges from 10.5 to 8.5mm in total length(6~14mm in thread length)	–	

10. Conclusions:

The subject and predicate device(s) share the same intended use, primary design and equivalent material of manufacture. The information provided in this submission including various test results support that the subject device is substantially equivalent to the predicate devices in the market.